

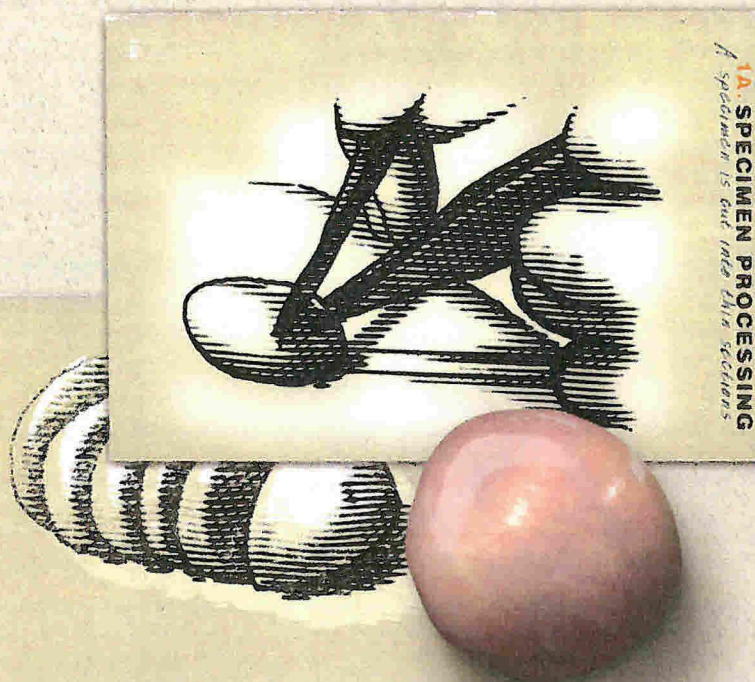
# **EXHIBIT E**

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Susan C. Lester  
Manual of  
**SURGICAL  
PATHOLOGY**



**THIRD EDITION**

**ELSEVIER  
SAUNDERS**



the primary care physician and other involved specialists (e.g., an oncologist caring for a cancer patient). If a rush reading is requested, the name or names of physicians to be contacted as well as a means to reach them (e.g., a beeper number or telephone number) must be provided.

#### Procedure Date

The date of the procedure (day, month, and year) must be documented in order to:

- Correlate the biopsy findings with other clinical tests (e.g., radiologic examinations or serum chemistries).
- Determine whether there is a delay during transport to the pathology department.
- Monitor turnaround time for pathology specimens.
- Fulfill requirements of Medicare/Medicaid and other third party payers for billing purposes.

The time the specimen was removed from the patient can be helpful to determine the length of time prior to fixation (which, if prolonged, can affect the results of some special studies). If the specimen is placed in a fixative for which the time of fixation is important (e.g., bone marrow biopsies in Zenker's fixative, formalin fixation for breast carcinoma specimens) the time of placing the specimen into fixative should also be recorded.

#### Adequate Clinical History

As for any medical consultation, the consultant can provide the most helpful additional information when an adequate history is provided. Clinical history helps define the need for, and the nature of, special studies that can be performed. It has been shown that pathologists cannot accurately predict clinical information from the glass slides alone.<sup>3</sup> Important elements of clinical history are listed at the beginning of each chapter for each type of specimen.

The Joint Commission requires that "surgical specimens are accompanied by pertinent clinical information and preoperative and postoperative diagnoses to the degree known" (Standard QC.2.30) and that "additional information required to select appropriate tests and to ensure accurate test interpretation and reporting of results (for example, race/ethnicity, family history, pedigree)" be provided (Standard IM.6.190) (Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing, 2009). Pertinent clinical history includes:

#### Purpose of removal of the specimen and the type of specimen

- Diagnostic biopsy
- Resection of tumor or re-excision of tumor site
- Surgery for therapeutic purposes (e.g., a colostomy take-down or joint replacement)

**Note:** The purpose of the surgery often determines the type of pathologic examination required (e.g., inking of

margins or tissue allocation for special studies). Inaccurate or insufficient labeling may lead to a suboptimal pathologic examination. The type of specimen is also important for accurate billing.

#### Location and types of any lesions present

- Description by anatomic site (e.g., head of pancreas) or region (e.g., upper outer quadrant)
- Identification by placement of a suture or staple
- Identification by radiologic imaging (e.g., radiography for breast calcifications or clips; nuclear imaging for octreotide uptake)
- Number of lesions and distance between lesions

Some lesions that are grossly evident in vivo may become less evident after excision and cessation of blood flow (e.g., vascular lesions, cystic lesions if incised). It may be necessary to mark some cancers with clips prior to neoadjuvant treatment as after treatment some cancers are no longer grossly identifiable.

#### Prior diagnoses

- History of prior known tumors (including type/site/date of removal/ stage of disease)
- Current or recent pregnancy. Pregnancy-related changes can mimic malignancies.
- Immune system status. It is important to know whether the patient may be immunocompromised:

HIV positive  
Organ transplants  
Chronic ambulatory-  
peritoneal dialysis  
Indwelling catheters or  
monitoring devices

Assisted ventilation  
Extensive burns  
Chronic sinusitis  
Diabetes

This information is important to help guide special studies (i.e., characteristic histologic responses to infectious disease organisms may be absent), to interpret histologic findings, and to aid in ensuring the safety of pathology personnel handling specimens with infectious organisms.

#### Prior or current treatment

- Radiation or chemotherapy. Treatment-related changes can be mistaken for malignancy if this history is not provided. Carcinomas can be difficult to find grossly after treatment, although extensive disease may be present microscopically. Identification of the tumor bed is important in order to assess response to treatment.
- Drug use that can alter the histologic appearance of tissues (especially important for the evaluation of liver and endometrial biopsies)
- Drug use that could make the patient susceptible to unusual infections (corticosteroid therapy, chemotherapy, prophylactic antibacterial or antifungal therapy)